

# Findings released from 1 of the largest percutaneous coronary intervention trials ever

May 23 2008

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A study led by Gregg W. Stone, M.D., professor of medicine at Columbia University Medical Center/New York-Presbyterian and chairman of the Cardiovascular Research Foundation, has shown that heart attack patients who were administered the direct thrombin inhibitor bivalirudin during primary angioplasty had a reduced rate of adverse clinical events, a lower rate of major bleeding, and a lower mortality rate than those who were treated with a regimen of heparin and glycoprotein IIb/IIIa inhibitors (GPI).

In the landmark global trial, bivalirudin was compared to heparin plus GPI in more than 3,600 patients with ST-segment (a specific electrocardiogram wave) elevation myocardial infarction (STEMI), the most severe form of heart attack. The findings from the trial are presented in the May 22, 2008 issue of the New England Journal of Medicine.

The HORIZONS-AMI trial is a prospective, single-blind, randomized, multicenter study conducted in 11 countries. A total of 3,602 patients undergoing angioplasty were randomly assigned to receive either bivalirudin with provisional use of GPI or heparin plus GPI. The two primary endpoints of the trial were major bleeding and net adverse clinical events, a composite of major adverse cardiovascular events (death, reinfarction, stroke or ischemic target vessel revascularization) or major bleeding at 30 days.

The secondary endpoint was major adverse cardiovascular events at 30 days. Those patients receiving bivalirudin within 30 days had significantly reduced net clinical adverse events by 24 percent, as well as reduced the risk of overall mortality by 33 percent and cardiac mortality by 38 percent, when compared to a regimen of heparin and GPI.

“The HORIZONS-AMI data show that using bivalirudin instead of heparin with a GPI during angioplasty increases survival in heart attack patients who are at high risk for death or disability,” Dr. Stone said. “As the first multicenter randomized primary angioplasty trial since the introduction of balloon angioplasty to show improved survival, we expect HORIZONS-AMI to have an immediate impact on which drug therapy cardiologists choose for their patients with heart attack.”

HORIZONS-AMI is the largest study ever to focus on the appropriate use of anticoagulant medications in patients experiencing STEMI and undergoing primary percutaneous coronary intervention (PCI). Only 7.2 percent of patients in the bivalirudin group received provisional GPI.

The study also found that bivalirudin significantly reduced rates of major bleeding by 40 percent and demonstrated comparable rates of major cardiovascular adverse events. Bivalirudin has previously been shown to result in less bleeding and similar rates of composite ischemia compared to heparin plus GPI in patients undergoing angioplasty for stable angina, unstable angina and non-ST-elevation myocardial infarction (NSTEMI).

Dr. Stone emphasized the importance of reducing the risk of bleeding. “In multiple previous trials, major bleeding has been shown to be a strong predictor of short and long-term mortality in patients undergoing angioplasty and in those with acute coronary syndromes,” he said.

Source: Columbia University

Citation: Findings released from 1 of the largest percutaneous coronary intervention trials ever (2008, May 23) retrieved 18 April 2024 from <https://medicalxpress.com/news/2008-05-largest-percutaneous-coronary-intervention-trials.html>

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